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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/614,076	07/03/2003	Leigh H. English	MECO:218-1 11792.0218.DVU	8919
7590	03/01/2005		EXAMINER KUBELIK, ANNE R	
Ms. Patricia A. Kammerer Howrey Simon Arnold & White, LLP 750 Bering Drive Houston, TX 77057-2198			ART UNIT 1638	PAPER NUMBER

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/614,076

Applicant(s)

ENGLISH ET AL.

Examiner

Anne R. Kubelik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34 and 36-43 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 34 and 36-43 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 34 and 36-43 are pending.
2. Amended claim 34, filed 29 July 2003, does not correspond to claim 34 as originally filed. There are amendments to the claim that are not properly marked up.
3. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

Sequence identifiers are missing from either the legend or the Brief Description of Figure 17A-C.

Full compliance with the sequence rules is required in response to this Office action. A complete response to this Office action must include both compliance with the sequence rules and a response to the issues set forth herein. Failure to fully comply with both of these requirements in the time period set forth in this Office action will be held to be non-responsive.

Claim Objections

4. Claims 34 and 38-39 are objected to because of the following informalities:

In claim 34, line 2, "comprising" should be replaced with --wherein the method comprises--.

In claim 38, line 1, and claim 39, line 1, "comprising" should be replaced with --, wherein the method comprises--.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34 and 36-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase “one or more point mutations ... Lys189 to Gly” in claim 1, lines 5-8, claim 38, lines 3-7, and claim 39, lines 5-8, or for the phrase “further comprises the amino acid substitutions ... Gln348 to Arg” in claim 37, lines 2-3, claim 38, lines 8-10, claim 39, lines 13-15, and claim 40, lines 2-4. Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 41-43 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicant regards as the invention. Dependent claims are included in all rejections.

Claims 41-43 are indefinite in their recitation of "a gene encoding a modified Cry3Bb* polypeptide". It is not clear if the gene is the same one with which the parent plant was transformed or if the claimed seed or plant comprises some other modified Cr3Bb* polypeptide.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 34 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8 and 14 of U.S. Patent No. 6,501,009.

Although the conflicting claims are not identical, they are not patentably distinct from each other. The method of producing a maize plant transformed with a nucleic acid encoding Cry3Bb.11098, which has a Asp165 to Gly mutation, as claimed in the issued patent, is species of the genus of methods of producing plants transformed with a nucleic acid encoding a Cry3Bb* with one or more of the amino acid substitutions Leu158 to Arg, Ser160 to Asn, Lys161 to Pro, Pro162 to His, Asp165 to Gly, and Lys189 to Gly. The method claimed in the issued patent would require that the nucleic acid be operably linked to a promoter in order to get

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expression of the nucleic acid and be comprised within a vector for success in methods of transformation.

11. Claims 34 and 36-43 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-25 of U.S. Patent No. 6,620,988. Although the conflicting claims are not identical, they are not patentably distinct from each other. The method of producing a plant transformed with a nucleic acid encoding a Cry3Bb* with one or more of the amino acid substitutions Leu158 to Arg, Ser160 to Asn, Lys161 to Pro, Pro162 to His, Asp165 to Gly, and Lys189 to Gly, as claimed in the issued patent, is species of the genus of methods of producing plants transformed with a nucleic acid encoding a Cry3Bb* with one or more of the amino acid substitutions Leu158 to Arg, Ser160 to Asn, Lys161 to Pro, Pro162 to His, Asp165 to Gly, and Lys189 to Gly. The method of producing a plant transformed with a nucleic acid encoding a Cry3Bb* with one or more of the amino acid substitutions Leu158 to Arg, Ser160 to Asn, Lys161 to Pro, Pro162 to His, Asp165 to Gly, and Lys189 to Gly, and further comprising one or more of the amino acid substitutions His231 to Arg, Ser311 to Leu, Asn313 to Thr, Glu317 to Lys, and Gln 348 to Arg, as claimed in the issued patent, includes the method of producing a plant transformed with a nucleic acid encoding a Cry3Bb* with one or more of the amino acid substitutions Leu158 to Arg, Ser160 to Asn, Lys161 to Pro, Pro162 to His, Asp165 to Gly, and Lys189 to Gly, and further comprising one or more of the amino acid substitutions His231 to Arg, Ser311 to Leu, Asn313 to Thr, Glu317 to Lys, and Gln 348 to Arg, as claimed in the instant application. Plants so transformed, seeds and progeny claimed in the issued patent include plants, seeds and progeny claimed in the instant application.

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12. Claims 34 and 36-43 are free of the prior art, given the failure of the prior art to teach or suggest

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (571) 272-0801. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. The central fax number for official correspondence is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Anne R. Kubelik, Ph.D.
February 18, 2005



ANNE KUBELIK
PATENT EXAMINER